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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,890	10/22/2003	Hans Locher	1529/2002	6834

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EXAMINER	
HUYNH, CARLIC K	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
05/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,890	LOCHER, HANS	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 18-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12 February 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-19 are pending in the application, with claims 16-17 having been withdrawn from consideration, in response to the restriction requirement submitted on November 1, 2006. Accordingly, claims 1-15 and 18-19 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election of the claims of Group I, namely claims 1-15 and 18-19, in the reply filed on April 2, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 18-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on April 2, 2007.

3. Applicants' election of (1) the compound of the Formula (I) as disclosed in example 42 (page 34 of the specification), in the reply filed on April 2, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The election/restriction requirement is deemed proper and is made FINAL.

Information Disclosure Statement

The Information Disclosure Statement submitted on February 12, 2004 is acknowledged.

Oath/Declaration

It does not identify the citizenship of each inventor. "Swiss" is not a proper country. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-15 and 18-19 provide for the use of use of a compound of Formula (I), but because the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicants are intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-15 and 18-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, e.g., results in a claim which is not a proper process claim under 35 U.S.C. 101. See

for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). However, in order to advance prosecution these claims will be treated as method claims.

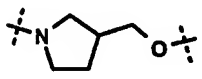
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-5 and 7-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Hubschwerlen et al. (WO 03/032962).

Hubschwerlen et al. teach compounds of Formula (I) and methods of treatment of bacterial infections, including enterococci, comprising a compound of Formula (I), where X is N, Y is CR6, n is 0, R1 is H, R2 is F, R3 is a C3-C6 cycloalkyl, R4 is -NHCOMe, R6 is H, and A is



(pages 2-3; page 92, lines 4-5; page 93, lines 2 and 11-13; and page 98, lines 20-25).

Hubschwerlen et al. also teach treatment with the compounds of Formula (I) under physiological conditions (page 1, line 6). It is wildly understood to one skilled in the art that physiological conditions are of neutral pH, where pH is 7.

Since Hubschwerlen et al. teach treatment with compounds of Formula (I) under physiological conditions and that physiological conditions are of neutral pH, the limitations of instant claim 1 have been met.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited reference. The claims are therefore properly rejected under 35 U.S.C. 102 (e).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hubschwerlen et al. (WO 03/032962).

Hubschwerlen et al. further teach compounds of Formula (I) have different optical isomers according to the Cahn-Ingold-Prelog nomenclature system and all the isomers are similarly useful (page 4, lines 20-26).

Since Hubschwerlen et al. teach compounds of Formula (I) have different optical isomers and all the isomers are similarly useful, it would be obvious to one skilled in the art at the time of the invention to use any one of the optical isomers, such as the (S) isomer.

8. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hubschwerlen et al. (WO 03/032962), as applied to claims 1-5 and 7-15 above, in view of Leach et al. (US 2004/0147441).

Hubschwerlen et al. teach broadly the employment of the compounds of Formula (I) against bacterial infections in humans (page 1, lines 8-9).

Hubschwerlen et al. do not teach the acidic environment of the bacterial infection.

Leach et al. teach methods and compositions useful for treating bacterial infections comprising quinolone and oxazolidinone compounds and the quinolone and oxazolidinone compounds dissolve in the mildly acidic or neutral pH environment of the small intestine (abstract; page 2, paragraph [0022]; and page 6, paragraph [0054]). Furthermore, the quinolone and oxazolidinone compounds are used for targeted release to the colon (page 6, paragraph [0054]).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the compounds and methods of treatment of a bacterial infection comprising a compound of Formula (I) of Hubschwerlen et al. to be used to treat bacterial infections in acidic environments because the compounds and methods of Leach et al. teach quinolone and oxazolidinone compounds dissolve in mildly acidic or neutral pH and can be used for targeted release to the colon and according to Leach et al., quinolone and oxazolidinone compounds can be used in environments of mildly acidic or neutral pH.

The motivation to combine the teachings of Hubschwerlen et al. to the teachings of Leach et al. is that the compounds and methods of Leach et al. can be used in environments of mildly acidic or neutral pH.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hubschwerlen et al. (WO 03/032962), as applied to claims 1-5 and 7-15 above, in view of Hill et al. (US 2002/0025924).

Hubschwerlen et al. do not teach bacterial infections in inflamed tissues and/or abscesses.

Hill et al. teach pharmaceutical compositions of and methods of producing quinolone and oxazolidinone compounds for administration into an abscess (abstract; and page 24, paragraphs [0191] and [0195]).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the compounds and methods of treatment of a bacterial infection comprising a compound of Formula (I) of Hubschwerlen et al. to be used to treat bacterial infections in inflamed tissues and/or abscesses because the compounds and methods of Hill et al. teach quinolone and oxazolidinone compounds can be administered into an abscess and according to Hill et al., quinolone and oxazolidinone compounds can be administered into an abscess.

The motivation to combine the teachings of Hubschwerlen et al. to the teachings of Hill et al. is that the compounds and methods of Hill et al. can be administered into an abscess.

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28 and 53 of copending Application Hubschwerlen et al. (10/554,732). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 28 and 53 of Hubschwerlen et al. are directed at a method of treating anthrax or an infection comprising administering a compound of Formula (I), which is the same compound of Formula (I) being used in the instant claim 1. Thus the compound of Formula (I) is not patentably distinct between Hubschwerlen et al. and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

Conclusion

11. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

S. Wang

SHENGJUN WANG
PRIMARY EXAMINER